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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,751	12/08/2003	Stavros C. Manolagas	3650.1003-007	4492

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EXAMINER

SHAFFER, SHULAMITH H

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,751

Applicant(s)

MANOLAGAS ET AL.

Examiner

Shulamith H. Shafer, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4-8 and 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/16/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims

The Art Unit location of your application in the USPTO has changed. The Examiner prosecuting your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Shulamith H. Shafer, Art Unit 1647.

Applicants' election, without traverse of Group II, claims 13-18, drawn to a method of screening for compounds that increase bone mineral density, in the reply filed on 6 March 2006, in response to the 8 July 2005 office action is acknowledged. Applicants have elected, without traverse, *in vitro* screening as the method to be searched.

Claims 1, 2, 4-8 and 10-18 are pending in the instant application. Claims 1, 2, 4-8, and 10-12 are withdrawn as being drawn to non-elected inventions. Claims 13-18 are under consideration to the extent they read on the elected invention.

Objections

Specification:

This application appears to be a division of Application No. 09/413,958, filed 7 October 2003, now US 6,660,468, however in amendment to the specification, dated 8 December, 2003, it is identified as a continuation of Application No. 09/413,958. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." The divisional application should set forth the portion of the earlier disclosure that is germane to the invention as

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claimed in the divisional application. Appropriate correction is required to correctly identify this application as a divisional.

Information Disclosure Statement

The information disclosure statement filed 18 August 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because many of the references appear to be lost (those the examiner did not specifically initial). Applicant is requested to provide courtesy copies of the missing papers (other than those identified on sheet 4 of 8 as AS3, AY3, and on sheet 5 of 8 as AU4 and AX4) with response to this office action. If these references are submitted with response to this office action, the references will be considered as if filed with the original IDS.

Specification

The disclosure is objected to because of the following informalities: In the brief description of the drawings on page 8, line 18 bridging page 9, line 2, Panels 2A and 2B are not specifically identified and described. Appropriate correction is required.

Claims

Claims 13-18 are objected to as encompassing non-elected inventions. All claims read as encompassing both the elected invention, *in vitro*, and the non-elected invention, *in vivo*. Appropriate correction is required.

Claim Rejections

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 16, the independent claims of the instant invention, are both drawn to screening methods that recite the same method steps. Step (a) of both claims recites "contacting osteoblast and osteocyte cells with either a glucocorticoid or a test compound". Are the osteoblasts and osteocyte cells together in the same preparation or are they separate? Step (b) of both claims recites "comparing the number of said cells". It is unclear which cells are intended: osteoblast cells, osteocyte cells or both. Step (b) goes on to recite "treatment with said glucocorticoid and said test compound". Does the step entail treating cells with glucocorticoid alone, or test compound alone, or both compounds at the same time.

Additionally, the claims are also indefinite because the exact same method steps are recited to indicate two different goals. Claim 13 recites a method for screening for compounds that stimulate bone development; claim 16 is drawn to a method for screening for compounds that increase bone mineral density. Essential method steps are missing. How would one of skill in the art discern the steps required to achieve each of the different recited goals?

Claims 15 and 18 are vague in the recitation of "determination of said apoptosis is selected from the group consisting of". Do applicants intend to select from a group of assay techniques? Furthermore the claims recite "determination of said apoptosis from the group consisting ofDNA fragmentation". Do applicants intend to fragment DNA or assay for DNA fragmentation as an indication of apoptosis?

Claims 14 and 18 are included in this rejection as depending from claims 13 and 16.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jilka et al. (1997, J of Bone and Mineral Res. 12 (supplement) S455, abstract S411). The claims recite the following method steps: a. contacting cells *in vitro* with either a glucocorticoid or a test compound; and b. comparing the number of cells undergoing apoptosis following treatment (Claims 13, 14 and 16, 17). Apoptosis is determined by TUNEL method (Claims 15 and 18).

Jilka et al. teach incubating osteoblasts with dexamethosone (a glucocorticoid) and/ or IL-6 (a test compound) and assessing the number of apoptotic cells. Apoptotic cells were identified by visual inspection using the TUNEL technique and quantified by a spectrophotometric assay. Thus, the teachings of Jilka anticipate all the limitations of claims 13-18.

Conclusions:

No claims allowed.

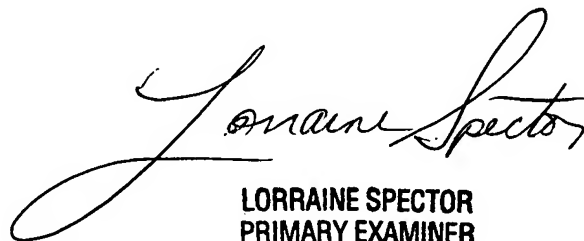
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHS



LORRAINE SPECTOR
PRIMARY EXAMINER